REMARKS/ARGUMENTS

In the specification, spelling and grammatical errors have been corrected. Also, terminology used to describe therapies of the prior art have been amended to more accurately describe the state of the art and to eliminate confusion with trade names utilized in the art. A Substitute Specification is submitted due to the amount of corrections submitted. The Substitute Specification includes no new matter. Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

In the Abstract, terminology used to describe therapies of the prior art have been amended to more accurately describe the state of the art and to eliminate confusion with trade names utilized in the art.

Claims 1-5 and 7-10 remain in this application. Claim 6 has been cancelled. Claim 7 has been previously amended. Claim 11 has been added. The following issues are outstanding in the Office Action dated February 19, 2003:

- Claims 1-5 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Argenta et al. WO 94/20041 (hereinafter referred to as "Argenta") in view of Collyer et al. U.S. Patent No. 5,973,221 (hereinafter referred to as "Collyer").
- Claims 1 and 7-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fleischmann U.S. Patent No. 5,973,221 (hereinafter referred to as "Fleischmann") in view of Collyer.

Applicant respectfully traverses the rejections and objections, and in light of the following remarks requests reconsideration and withdrawal thereof.

Claim Rejections – 35 USC §103(a): Argenta in view of C llyer

Examiner has rejected Claims 1-5 and 7 under 35 U.S.C. §103(a) as being unpatentable over Argenta in view of Collyer. A device is unpatentable under §103 only if it would have been obvious to one of ordinary skill in the art at the time of the invention to combine aspects of the references to obtain the invention. Applicant respectfully asserts that Claims 1-5 and 7 are not obvious in view of Argenta and Collyer, and that the pad of the present invention is distinct from the pad of Collyer.

Applicant notes, as the Examiner has indicated, that Collyer teaches a porous pad that can be impregnated with antiseptic and/or other medicament (col. 3, lines 53-56). Applicant notes, however, that the present invention claims a porous pad being *predisposed* with a *wound healing factor* (emphasis added). Applicant respectfully asserts that this element of the present invention is distinct from Collyer. The present invention claims a pad "predisposed" with an agent as opposed to being "impregnated" as disclosed in Collyer. Applicant asserts that the pad being predisposed with an agent is distinct from one impregnated with an agent, as "predisposed" is intended to claim the agent as formed with the pad in the present invention (please see page 2 line 34 through page 3, line 3 of the present application), while Collyer discloses a pad "impregnated" with an agent, which is to imply saturating or soaking a material with the agent. Support for this definition can be found in the *Encarta World English Dictionary* (published 1999), which defines impregnate as "saturate to incorporate a chemical into a porous material such as wood or cloth, especially by soaking it thoroughly with a liquid." The distinction between the present invention and Collyer is that the present invention claims an agent predisposed with the pad, such as by grafting, whereas the agent of Collyer is merely within the

dressing material. New claim 11 has been added to further distinguish the present invention from the prior art.

Additionally, Collyer makes no mention of impregnating its dressing with a "wound healing factor" such as bFGF as claimed in the present invention. The purpose of the present invention is to aid wound healing by reepithelializing the wound (please see page 3, lines 9-10 of the present application). The introduction of wound healing factors, such as bFGF, as claimed in the present invention, are specifically intended to promote reepithelialization. In contrast, the desired effect of Collyer is to prevent infection of the wound (please see Column 7, lines 4-6). As such, Collyer only teaches impregnation of its dressing with infection prevention agents, such as antiseptics.

There is no motivation to combine the teachings of Argenta with the teachings of Collyer in order to achieve the present invention. Applicant respectfully asserts that combining these references would in fact NOT achieve the desired result of the present invention by the means claimed in the present invention (reepithelialization by predisposing growth factors into a negative pressure system). There is no motivation in the prior art to modify Collyer to be predisposed with growth factor to achieve the present invention. As such, it would not be obvious to one with ordinary skill in the art to substitute the porous pad of Argenta for the porous pad of Collyer for more efficient wound healing. As Applicant has asserted, the pad of the present invention is distinct from the pad of Collyer.

Claim Rejections – 35 USC §103(a): Argenta in view of Collyer

Examiner has rejected Claims 1 and 7-10 under 35 U.S.C. §103(a) as being unpatentable over Fleischmann in view of Collyer. A device is unpatentable under §103 only if it would have been obvious to one of ordinary skill in the art at the time of the invention to combine aspects of

the references to obtain the invention. Applicant respectfully asserts that Claims 1 and 7-10 are not obvious in view of Fleischmann and Collyer, and that the pad of the present invention is distinct from the pad of Collyer.

Similar to the arguments mentioned above, there is no motivation to combine the teachings of Fleischmann with the teachings of Collyer in order to achieve the present invention. Applicant respectfully asserts that combining these references would in fact NOT achieve the desired result of the present invention by the means claimed in the present invention (reepithelialization by predisposing growth factors into a negative pressure system). There is no motivation in the prior art to modify Collyer to be predisposed with growth factor to achieve the present invention. As such, it would not be obvious to one with ordinary skill in the art to substitute the porous pad of Fleischmann for the porous pad of Collyer for more efficient wound healing. As Applicant has asserted, the pad of the present invention is distinct from the pad of Collyer.

SUMMARY

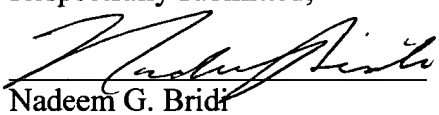
In view of the above, it is submitted that the claims are in a condition for allowance. Reconsideration and withdrawal of the rejections and objections are hereby respectfully requested. Allowance of Claims 1-5 and 7-11 at an early date is solicited.

If upon consideration of the above, the Examiner should feel that outstanding issues remain in the present application that could be resolved, the Examiner is invited to contact the undersigned at the telephone number indicated to discuss resolution of such issues.

Also, attached hereto is a marked-up version of the changes made to the Specification by the current amendment. The attached Substitute Specification is captioned **"Version with markings to show changes made."**

Applicant respectfully requests favorable consideration.

Respectfully submitted,



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SPECIFICATION

WOUND THERAPY ~~VACUUM ASSISTED CLOSURE~~ SYSTEM WITH PROVISION FOR INTRODUCTION OF AGENT

RELATED APPLICATION:

[0001] This application claims priority to United States provisional application Serial No. 60/127,595 entitled VACUUM ASSISTED CLOSURE SYSTEM WITH PROVISION FOR INTRODUCTION OF AGENT filed April 2, 1999. By this reference, the full disclosure, including the drawings, of U.S. provisional patent application Serial No. 60/127,595 is incorporated herein.

TECHNICAL FIELD:

[0002] The present invention relates to the healing of wounds. More specifically, the present invention relates to the ~~vacuum assisted closure (VAC)~~ negative pressure therapy of wounds, commercialized as Vacuum Assisted Closure®, or V.A.C.®, by Kinetic Concepts, Inc. of San Antonio, Texas, and wherein a growth factor or other agent is introduced to a wound site through grafting with a ~~VAC~~ pad in order to facilitate wound healing.

BACKGROUND ART:

[0003] Wound closure involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow through damaged or broken vessels is stopped by capillary level occlusion, whereafter cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such

wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

[0004] Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until recently, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the insertion points, which can eventually cause wound dehiscence and additional tissue loss.

[0005] Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalization, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

[0006] As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for ~~draining~~ healing wounds by applying continuous negative pressures have been developed. When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous

tissues. In practice, the application to a wound of negative pressure, commonly referred to as ~~vacuum assisted closure (VAC) therapy~~ negative pressure wound therapy (NPWT) and commercialized as Vacuum Assisted Closure®, or V.A.C.®, by Kinetic Concepts, Inc. of San Antonio, Texas, typically involves mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, ~~VAC~~ NPWT therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

[0007] While ~~(VAC)~~ negative pressure wound therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. Because the inflammatory process is very unique to the individual patient, even the addition of ~~(VAC)~~ negative pressure wound therapy does not result in a fast enough response, especially during the occlusion and initial cleanup and rebuilding stages, for adequate healing of some wounds. It is therefore a principle object of the present invention to provide a method and apparatus whereby the known ~~(VAC)~~ negative pressure wound therapy modalities are improved through the introduction of growth factors and/or other agents that facilitate wound healing.

DISCLOSURE OF THE INVENTION:

[0008] In accordance with the foregoing objects, the present invention – a method and apparatus for the introduction to a wound undergoing ~~vacuum assisted closure (VAC)~~ negative pressure wound therapy of a wound healing agent – generally comprises a foam pad for insertion substantially into a wound site and a wound drape for sealing enclosure of the foam pad at the wound site. According to the invention, the foam pad is placed in fluid communication

with a vacuum source for promotion of ~~fluid drainage~~ wound healing. Additionally, the foam pad is predisposed, through grafting or other techniques known to those of ordinary skill in the art, with basic fibroblast growth factor (bFGF), anti-microbials or other factors, also known to those of ordinary skill in the art, for the promotion of increased wound healing.

[0009] According to the preferred method of the present invention, a growth factor or other wound healing agent is added to the previously known ~~VAC~~ negative pressure therapy through modification as necessary of the ~~VAC system's~~ foam pad. Such growth factors as the basic fibroblast growth factor (bFGF) are known to accelerate wound healing due to their potent angiogenesis and granulation tissue formation activities. As has been demonstrated even with difficult to heal wounds, such as infected wounds, burn wounds, and diabetic wounds, the resultant activities lead to the rapid ~~reepitherialization~~ reepithelialization and contraction of the wound. The combination of ~~VAC~~ negative pressure therapy with growth factor introduction, through the modification of the foam pad and predisposition thereof with the bFGF, is therefore thought to be an important contribution to the wound healing arts.

[00010] Finally, many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing discussions, the following drawing and exemplary detailed description and the claims appended hereto.

BRIEF DESCRIPTION OF THE DRAWINGS:

[00011] Although the scope of the present invention is much broader than any particular embodiment, a detailed description of the preferred embodiment follows together with an illustrative figure, wherein like reference numerals refer to like components, and wherein:

[00012] Figure 1 ~~The figure~~ shows, in partially cut away perspective view, the preferred embodiment of the present invention as applied to a mammalian wound site.

BEST MODE FOR CARRYING OUT THE INVENTION:

[00013] Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention – ~~a vacuum assisted closure~~ wound therapy system with provision for introduction of an agent, the scope of which is limited only by the claims appended hereto.

[00014] Referring now to ~~the figure~~ Figure 1, the present invention 10 is shown to generally comprise a foam pad 11 for insertion substantially into a wound site 12 and a wound drape 13 for sealing enclosure of the foam pad 11 at the wound site 12. According to the invention, the foam pad 11 is placed in fluid communication with a vacuum source for promotion of ~~fluid drainage~~ wound healing. Additionally, the foam pad 11 is predisposed, through grafting or other techniques known to those of ordinary skill in the art, with basic fibroblast growth factor (bFGF), antimicrobials or other factors, also known to those of ordinary skill in the art, for the promotion of increased wound healing.

[00015] According to the preferred embodiment of the present invention, the foam pad 11, wound drape 13 and vacuum source are implemented as known in the prior art, each of which is detailed in U.S. patent application Serial No. 08/517,901 filed August 22, 1995. By this reference, the full disclosure of U.S. patent application Serial No. 08/517,901 ("the '901 application"), including the claims and drawings, is incorporated herein as though now set forth in its entirety. Additionally, such a negative pressure wound therapy ~~VAC~~ therapy system is

readily commercially available through Kinetic Concepts, Inc. of San Antonio, Texas, U.S.A. and/or its subsidiary companies through its V.A.C.® product line.

[00016] As detailed in the '901 application, the foam pad 11 preferably comprises a highly reticulated, open-cell polyurethane or polyether foam for good permeability of wound fluids while under suction, but in this application may comprise a conventional sponge cellulose type dressing as necessary for introduction of the desired agent. As also detailed in the '901 application, the foam pad 11 is preferably placed in fluid communication, via a plastic or like material hose 14, with a vacuum source, which preferably comprises a canister safely placed under vacuum through fluid communication, via an interposed hydrophobic filter, with a vacuum pump. Finally, the '901 application also details the wound drape 13, which preferably comprises an elastomeric material at least peripherally covered with a pressure sensitive, acrylic adhesive for sealing application over the wound site 12.

[00017] According to the preferred method of the present invention, those components as are described in the '901 application are generally employed as known in the art with the exception that the foam pad 11 of the present invention is modified as necessary for the introduction of a growth factor. Such growth factors as the basic fibroblast growth factor (bFGF) are known to accelerate wound healing due to their potent angiogenesis and granulation tissue formation activities. As has been demonstrated even with difficult to heal wounds, such as infected wounds, burn wounds and diabetic wounds, the resultant activities lead to the rapid ~~reepitherialization~~ reepithelialization and contraction of the wound. The combination of ~~(VAC)~~ negative pressure therapy with growth factor introduction, though the modification of the foam pad 11 and predisposition thereof with the bFGF, is therefore thought to be an important contribution to the wound healing arts. Likewise, the present method presents an excellent

opportunity for the introduction to the wound site 12 of anti-microbial agents, whether alone or in combination with bFGF or other agents.

[00018] While the foregoing description is exemplary of the preferred embodiment of the present invention, those of ordinary skill in the relevant arts will recognize many variations, alterations, modifications, substitutions and the like as are readily possible, especially in light of this description, the accompanying drawings and the claims drawn hereto. For example, those of ordinary skill in the art will recognize that while the preferred embodiment of the present invention comprises grafting the desired agent onto the foam pad 11 of the ~~VAC~~ negative pressure therapy system, those of ordinary skill in the art, with the benefit of this exemplary disclosure, will readily recognize many substantially equivalent modes for introduction of the desired agent. For example, in the case of a foam pad 11 that has not been predisposed with an agent or that has been predisposed with an agent which, over time, has subsequently been exhausted into the wound site 12, the desired agent may be injected with a needle and syringe, or the like, through the wound drape 13 and into the foam pad 11. In any case, because the scope of the present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation of the present invention, which is limited only by the claims appended hereto.

INDUSTRIAL APPLICABILITY:

[00019] The present invention is applicable to the wound healing arts.